IMAGINE IF THE NEXT PAGE FEATURED EUROPE AS THE WORLD LEADER IN LIFE SCIENCES.

A Competitiveness Strategy for European Life Sciences

efpia

Imagine if Europe's Life Sciences Sector:

- **Delivered scientific and medical breakthroughs - first.**
- **Transformed the lives of patients and changed the course of public health.**
- **Achieved all this, while driving Europe's economic growth, resilience and security.**

That is our vision for the future of Europe's life sciences sector.

By creating a Competitiveness Strategy for European Life Sciences, overseen by an EU office of Life Sciences, we believe we can turn that vision in to a reality.

Why it matters:

The life sciences sector is one of Europe's most important strategic assets, delivering innovative medicines and vaccines that are fundamental to the long-term health and security of EU citizens. In recent decades we have seen HIV turned from a death sentence to a condition that can be managed, huge advances in cancer care transforming survival rates, hepatitis C can now be cured in 95% of patients, and there are new tools to stem the tide of the obesity epidemic and manage cardio-vascular disease.

The sector contributes more to the EU's trade balance than any other. Research-based pharmaceutical companies invest a greater percentage of their revenue back into research and development than any other sector and act as a catalyst for cutting-edge technologies like biotech, AI and digital health.

The pharmaceutical industry is responsible for about 21% of global research expenditure. It directly employs around 900,000 people across the region and indirectly generates over 2.5 million jobs.

At the same time, Europe's life science eco-system is facing intense pressure from the US and China where more ambitious, dedicated strategies are driving growth. Over the last two decades 25% of Europe's share of global R&D investment has been redistributed to other regions of the world. Similarly, our share of global clinical trials has fallen from 25.6% to 19.3% in the last decade. European biotechs are only able to access around 20% of the finance that their US counterparts can and today, nearly three-quarters of European science graduates choose to remain in the US in hubs like Boston and San Francisco after completing their doctorates.

Why now?

Against a backdrop of continued global insecurity, the EU leaders have underlined the importance of regaining Europe's competitive edge, enhancing our economic security and resilience. Geopolitical, societal, economic, health and climate challenges are driving the need for clear direction, unity as well as a sense of ambition.

Considering the 30-year trend in global R&D investment and activity, the time for action is now.

Take advanced therapies (ATMPs) like gene and cell editing; although Europe produces more scientific publications on ATMPs than any other region, clinical trial activity is twice as high in the US and almost three times as high in China.

Given the strategic and economic value of the life sciences sector and the challenges stemming from geopolitical instability, health and economic challenges and increased global competition, there is a strong case for action at the start of this new mandate.

New mandate, new approach - joined-up thinking and policy coherence

The current challenge is underlined by the difficulty to align the EU leaders' call for a more competitive Europe with a revision of the EU pharma legislation that will weaken the competitiveness of one of its most important sectors.

Regulatory reforms through the revision of the the EU pharma legislation will enhance Europe's life sciences offering. Strategic EU initiatives, such as the call to update the EU bioeconomy strategy and the European Economic Security Strategy offer an opportunity to secure and strengthen strategically important industries.

However, the erosion of IP rights combined with a continued lack of investment in health innovation, a fragmented capital market and a growing thicket of new regulation across different areas means the net impact makes it increasingly difficult to discover, develop and manufacture new medicines in Europe.

The Letta Report and imminent Draghi Report are important steps in the wider drive for European competitiveness but the multiplicity of legislation and initiatives that impact our sector underline the need for a coordinated Competitiveness Strategy for European Life Sciences overseen by an EU Office of Life Sciences that is accountable for its delivery.

What should the strategy include?

EFPIA calls on EU policymakers to adopt a new approach to its life sciences ecosystem, one that prioritises connecting the sector and securing EU competitiveness. Specifically, that means:

- **STRATEGY and LEADERSHIP – a Competitiveness Strategy for European Life Sciences overseen by an EU Office for Life Sciences that is accountable for its delivery.**
- **Policies to support the TRANSLATION of ideas into innovation and innovation into products and services.**
- **Building an eco-system for Europe to be THE LOCATION for developing and manufacturing new technologies.**
- **A commitment to INVEST in health innovation.**
- **Policies to SECURE Europe's future as a global biopharma player.**

Both the strategy and the EU Office for Life Sciences would need to connect the different policy fields of competencies in the European Commission, ensure a better overview of EU Member States´ best practices and reforms and ensure a better understanding of the sector. This new approach should be based on partnership and collaboration between policymakers focusing on EU-wide issues, those in the Member States and the wider Life Sciences industry and other key stakeholders. Together, just imagine what we could achieve.

Based on this urgent need, we propose the following key policy solutions.

1. EU STRATEGIC LEADERSHIP EXECUTED BY A LIFE SCIENCES OFFICE

The Life Sciences sector in the EU faces significant bureaucratic challenges due to a complex and fragmented regulatory environment, with responsibilities split across multiple Directorate-Generals (DGs) in the European Commission and regulators at EU and Member State level. This fragmentation leads to sometimes contradictory policy initiatives or regulation not adapted to the specificities of the sector, thereby limiting the sector's potential as an economic and innovation driver essential for maintaining Europe's global edge. Despite some efforts to streamline processes and improve market competitiveness, the lack of strategic coordination and oversight across policy domains leads to a continued compounding of regulatory burden on the sector. This stands in contrast to Europe's global competitors, who view Life Sciences as a strategic asset requiring a coherent strategy and comprehensive industry-wide consideration.

We urgently need a holistic approach, led by a dedicated Life Sciences office within the European Commission that can steer and coordinate policymaking guided by a clear vision to make Europe a world-leader in science, innovation and modern manufacturing, delivering for patients and society.

Policy solutions:

Strategic leadership: Leading the strategic direction of EU initiatives impacting the life sciences and biotechnology agenda and coordinating with national efforts to foster synergy and avoid duplication of efforts.

Policy coordination: Establish an EU Office of Life Sciences with clear responsibilities within the Commission to ensure alignment and coordination across all policy domains that impact the sector. Regularly engage with industry partners and stakeholders to gather insights on emerging trends and implementation barriers focusing on innovation and competitiveness.

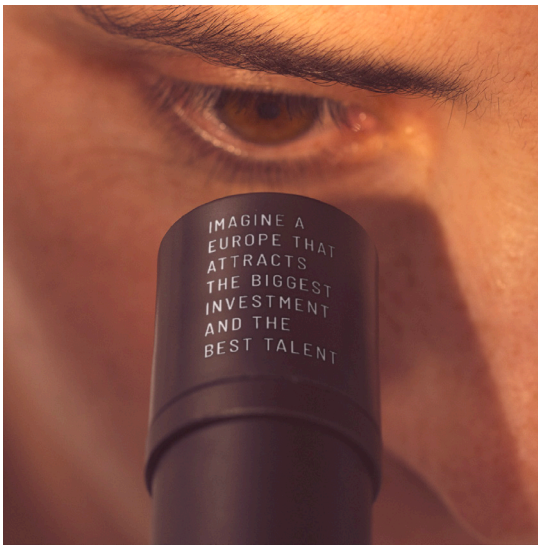
Competitiveness checks: Continuously evaluate the (incremental and cumulative) impact of new and existing policies and regulatory proposals, on the competitiveness of the EU's Life Sciences sector. Assess long-term trends in investment in R&D and manufacturing by comparing with major healthcare markets like the US, China, and Japan, and implement corrective measures when needed. This involves assessing regulatory frameworks, funding

Competitiveness check should include the following steps: quantitative analysis, evaluation (all regulatory proposals, including implementing and Delegated Acts), monitoring (continuous monitoring of regulatory outcomes to understand their long-term effects on competitiveness and benchmark with other regions), stakeholder consultations, sectoral reviews (regular sectoral reviews by the European Commission to assess the cumulative effect of regulations) and integration in policy discussions (discussions of the sectoral reviews in the COMPET and ECOFIN Councils).

mechanisms, and market conditions to maintain the EU's position as a leading global player.

Better regulation: Actively identify and implement measures to reduce bureaucratic hurdles that impede innovation and efficiency. To prevent unnecessary over-regulation, optimise existing structures and simplify administrative processes, reporting requirements, enhance regulatory clarity, and promote faster approval timelines for Life Sciences R&D and manufacturing projects. Special attention should be given to implementation of the green and digital agendas to ensure that the green and digital transitions are achieved in lockstep with improved innovation capacity and competitiveness for the sector.

2. EUROPEAN ECO-SYSTEM THAT TRANSFORMS IDEAS INTO INNOVATION



The European Health and Life Sciences sector is at a critical juncture; it could spearhead advancements in new technologies delivering for patients, society and the economy, or fall further behind. To address this requires an eco-system based approach. A coherent strategy would ensure that European biotech clusters can compete with the major US hubs like Boston and San Francisco. In terms of R&D, it would mean closing the gap which has widened from a €2 billion to a €25 billion gap compared to the US. It could re-invigorate the financing of pioneers – ensuring that firms starting up in Europe are nurtured and don't need to look abroad for financing or fail before they have a chance to deliver for European patients. It means reinventing partnership models to ensure Europe remains a world-leader in manufacturing and is ready to respond against the next pandemic or other health security crisis.

Policy solutions:

Foster competitive European biotech and pharmaceutical clusters - Support selected, specialised clusters of biotech and pharmaceutical excellence by strategic, targeted use of EU funds including Horizon Europe and future framework programs, looking at core enablers in globally successful clusters. Support promising incubator environments that work with start-ups.

Strengthen European capital markets - Enable European life-sciences venture capital (VC) funds at scale through EU guarantee funds supported by the European Investment Bank (EIB) and other financial vehicles, taking a more active role to invest in all stages of development. The Commission should also issue guidance and best practice to reform pension fund regulation at national level with the aim to enable pension funds to invest in life sciences venture capital, learning from geographies where they play a bigger role in innovation funding. Enhance the Capital Markets Union for better access to capital, and provide guidance on the use of national incentives to boost investment in high-risk innovative companies and SMEs, ensuring Europe's competitiveness in research and manufacturing.

EU framework programmes to foster partnerships and health security - Upgrade EU's Framework Programme with fit-for-purpose rules to attract industry to European programmes, partnerships, and clusters to power up Europe's translational research and manufacturing capacity and experiment with new collaboration and business models. Derogations and flexibility from the Commission's one-size-fits-all approach to corporate agreements should be possible

when necessary, by removing administrative burden and attracting in-kind contributions and expertise from companies that do not receive EU funding. Add fit-for-purpose financing tools for HERA for contracting late-stage development of pandemic Medical Counter-Measures.

Reinforce internationally competitive IP rights - Recent proposals to shorten regulatory data protection (RDP) and orphan market exclusivity (OME) and expand the Bolar exemption have reduced investor confidence in the IP framework, which will harm innovation by destabilising the investment environment. From a strategic perspective, there is a need for a predictable and enforceable IP system to provide legal certainty and encourage innovation and investment. Critical incentives, including Supplementary Protection Certificates (SPCs), patents, RDP, and Market Protection need not only to be granted in an efficient, predictable manner, but also be readily enforceable at the Member State level, thereby cementing EU competitiveness by ensuring that innovators are able to receive the benefit of granted incentives in practice.

3. GLOBALLY COMPETITIVE LOCATION FOR DEVELOPING AND MANUFACTURING NEW TECHNOLOGIES

Europe is competing globally to attract investment in research and manufacturing, and to be a priority location for clinical trials and for launching medicines. As set out above, metrics regarding the EU's ability to train and retain STEM students, the share of global R&D and clinical trials are moving in the wrong direction. To be competitive, we need to keep up with other regions but also look to the future.

In some areas, Europe is making progress, including the EU Pact for Skills, the European Alliance for Apprenticeships, and the EU Talent Pool Initiative, but more needs to be done. In others, it clearly falls behind.

Despite the adoption of the Clinical Trials Regulation, conducting **multi-country clinical trials** in Europe, in particular for the healthcare solutions of the future such as precision medicine, is burdensome and time consuming due to remaining regulatory fragmentation and lack of coordination, making trial sponsors chose other regions.

For critical enabling technologies such as **Artificial Intelligence**, the EU is leading on regulation but not in adoption and implementation that promotes innovation. The European Medicines Agency (EMA) has a workplan on how to facilitate the development and use of responsible and beneficial AI, and the recent communication promotes AI adoption in biotech through initiatives like "GenAI4EU" and investments in digital infrastructure to support the sector's growth but progress remains slower compared to other regions.

Furthermore, some **environmental and chemical policies** have unintended but highly negative consequences on the level-playing field between Europe and other regions, including potential medicines shortages due to chemical substance restrictions in the EU (for example of TiO2 and PFAS) without sufficient time to seek alternatives or allowing exemptions for pharmaceutical development and manufacturing building on a sound risk-based approach. The pharmaceutical industry is committed to taking decisive actions to reduce the environmental impacts across the value chain and we are leading the transition towards decarbonisation by setting ambitious science-based targets, investing in renewable energy and collaborating with stakeholders. To continue this progress without negatively affecting innovation or access to medicines, flexibility and support for innovation in the (re)development, manufacturing and supply of medicines to address climate, environment and sustainability targets should be a priority goal for regulators.

Policy solutions:

Double-down on education and life-long learning to meet skills needs - Promote STEM and address skill gaps by incorporating the Life Sciences sector in the European skills agenda. Support the R&D and manufacturing workforce in acquiring advanced digital and transversal skills, emphasising the need for continuous learning and adaptability. Enhance EU funding for STEM education, like the Marie Curie Program, to build a resilient and innovative workforce, focusing on retaining and attracting global STEM talent, including through cross-border mobility with international work permits for high-skilled workforce. Build on the proposal for establishing an EU Talent Pool adopted in 2023 as a key component of the Commission's Package on skills and talent mobility with recruitment options for STEM and Life Sciences relevant skilled workers.

Harmonised, agile, and enabling clinical trials ecosystem that supports multi-country clinical trials - The EU should deliver the true promise of EU Clinical Trials Regulation (CTR) through simplification and flexibility, support harmonized dossier review by National Competent Authorities and Ethics Committees across Europe for multi-country clinical trials, develop integrated processes for combined studies involving a medicinal product as well as a medical device or in-vitro diagnostic, encourage use of innovative technologies and methods, and exempt GMO-containing products from national approval for clinical trials.

Promote the effective access and use of health data to fuel research, development and manufacturing of innovative health technologies - To create a balanced ecosystem benefiting all stakeholders, the EU should support phased implementation of the European Health Data Space (EHDS) and AI Act in consultation with stakeholders, building on established solutions, adopt a risk-based cross-border approach to data flows, align with current practices for sharing of IP protected data, establish a common framework for real-world evidence, co-create AI approaches (for both R&D and manufacturing), ensure EMA oversight of the use of AI in medicines development and support the digitalisation of national health systems.

Attract investment in modern manufacturing through smart regulation:

- Support a balanced implementation of the EU Green Deal through a resilient supply chain transition plan based on robust science that ensures a level playing field in environmental and manufacturing standards and doesn't disproportionately impact innovation. Dialogue with industry on new proposed regulation should be facilitated by the Life Science Office.
- Shift regulatory provisions from EU secondary legislation to EMA guidance to enable simplification and an agile regulatory framework which is future-proof and enables innovation and global regulatory convergence.[1]

1. Including regarding Annex II of the proposed revision of the pharmaceutical directive and in relation to the revision of the Variation Regulation.

4. DELIVERING FOR SOCIETY AND THE ECONOMY THROUGH INVESTMENT IN HEALTH

Investing in health isn't just fundamental for the European social model - it's a potent catalyst for economic vitality and for economic and health security. This is a critical investment in which not only answer urgent health needs but also drive economic growth, innovation, environmental sustainability and productivity.

Investing in health, including through primary and secondary prevention approaches, yields profound societal and economic benefits. It protects not only individuals but entire communities. This strategic investment is essential not only for preventing disease but also for building resilient and effective health systems that underpin the European economy. Importantly, part of this investment is increasingly directed towards reducing the environmental footprint of Life Science sector operations, integrating green technologies and sustainable practices into the core of Life Science industries.

The Letta report emphasizes the need for a paradigm shift towards prioritising innovation. The report advocates for increasing healthcare budgets, prioritising investments in advanced health technologies, and blending funding mechanisms to ensure sustainable healthcare systems. It also highlights the importance of standardising digital tendering and common procurement rules across EU member states to improve efficiency and competitiveness. We support this but believe more needs to be done.

Policy solutions:

Boost investment in health systems - With an ageing population, increased burden of chronic disease, a shrinking workforce, and the impact of climate change, the EU must support Member States in enhancing their healthcare systems by driving investment through strategic funding, infrastructure upgrades, prevention, digitalisation, national framework conditions and green practices.

- Recognize health expenditure as an investment in the EU stability and growth pact, introducing a "golden rule" for certain health expenditure. The impact of these expenditures should be measured to ensure a return on investment through reduced health and social care costs, enhanced labor productivity, and increased fiscal revenue from health investments and industrial activities.
- Assist member states in identifying potential projects, preparing investment plans, and ensuring the strategic alignment of these investments with EU-wide goals.
- Set a minimum target for health expenditure in the European Semester to protect health budgets and analyse the return on investment of health spending across Member States.

Adopt European value-based procurement guidelines that consider broader criteria than price, including environmental standards and supply sustainability: Commission to develop and monitor the implementation of European guidelines on public procurement in all EU Member States based on the 'Most Economically Advantageous Tender (MEAT)' criterion and ensuring multiple tender winners.

5. SECURING EUROPE'S PLACE AS A GLOBAL BIOPHARMA PLAYER

The EMA is tasked with the critical role of regulating pharmaceuticals across Europe but faces significant challenges given the pace of innovative change. Resources are required – at the right level and focused on the right skills - to streamline current approaches and ensure EMA remains at the forefront of regulatory policy. Recognising these challenges, the Letta report proposes improvements to the EMA's PRIME scheme to better align with the FDA's expedited pathways for medicinal products meeting critical health needs. Furthermore, the Commission's recent Communication on Biotechnology suggests that simplifying the regulatory framework could significantly benefit biotech companies by reducing obstacles and accelerating market access.

In an era where global trade dynamics are continuously evolving, the need to ensure resilient supply chains is clear to all. The EU's success rests upon the pillars of free trade and openness, and the Life Sciences sector is not just essential in this regard; it's of strategic importance. Reconciling this means stable and secure access to both raw materials and finished products to mitigate the risk of global disruptions, and at the same time working with partners, including regulators and industry, to increase mutual reliance and enable the flow of critical goods to patients. By establishing sector-specific agreements with key partner countries, the EU can stabilise access to key materials and technologies, thereby reducing dependency in areas where vulnerabilities are identified. As well as securing supply for patients, the economic benefits of ambitious trade policies are substantial. For example, the EU-Canada CETA deal, which includes forward-looking IP and regulatory provisions for medicines, contributed to a 74% growth in EU pharmaceutical exports to Canada since 2016.

The urgency to act is clear. The EU's position as a leader in global healthcare and biotechnology innovation hinges on its ability to adapt and respond to these changing dynamics. Establishing strategic sector-specific open trade agreements is not merely a policy option; it is a necessity to secure the future resilience, autonomy, and competitiveness of Europe's industrial and economic landscape. This strategic move will not only safeguard against current vulnerabilities but also pave the way for a thriving, innovative, and robust European economy.

Policy solutions:

Ensure robust funding and resources for EMA and the European Medicines Regulatory Network.

This would enable Europe to:

- Match the ambitions for a future-proof regulatory framework proposed in the revision of the EU pharma legislation, making Europe more attractive as a region to launch new medicines first. Increased financial and human resources (specifically focus on building expertise) are needed to implement early advice, increased use of expedited regulatory pathways, more systematic use of Real World data and regulatory sandboxes.

- Strengthen international regulatory convergence, allowing Europe to lead internationally setting regulatory standards. The EU should strengthen its alignment with the US and other major regulators to prevent delays and barriers in access, ensuring EU companies can grow internationally and compete effectively. Unilateral reliance with trusted regulatory agencies should be fostered.

Establish strategic sector-specific open trade and partnership agreements on biotechnology and/or healthcare goods with trusted partner countries to enhance supply chain security, strategic autonomy, and competitiveness, address upstream dependency on raw materials and equipment for biomanufacturing.

Develop new tools and initiatives to attract Foreign Direct Investment in Life Sciences, such as strengthening existing EU platforms where national European trade and investment agencies exchange and coordinate to raise awareness of the needs, opportunities and innovation of the Life Sciences sector, and "Invest in EU" initiatives at high ministerial level.

Ensure full transition to electronic Product Information Leaflets (ePIL) across Member States to strengthen the supply chain, improve efficiency, transparency and environmental sustainability.

HOW WILL WE KNOW IF WE SUCCEED?

To effectively measure the progress made in enhancing the Life Sciences sector's contribution to strategic autonomy, environmental sustainability, and industrial competitiveness within the EU, several key metrics can be proposed:

EU - Strategic leadership executed by a Life Science Office	
Competitiveness checks	• The most visible metric will be how often competitiveness checks are applied to regulation and rules affecting the Life Sciences sector and how often this affects the outcome.
Stakeholder dialogues	• Number of dialogues with stakeholders in the life science eco-system.
European eco-system that transforms ideas into innovation	
Competitiveness of European biotech and pharmaceutical clusters	• Rankings and scores in global innovation indexes specifically tailored to life sciences.
Global share of R&D investment	• The relative share of total private investment in R&D in life sciences (also looking at each segment, e.g. biopharmaceuticals, vaccines, medical devices etc).
Private equity investment	• Value of venture capital funding received by biotech and pharmaceutical startups, compared to other regions.
Globally competitive location for developing and manufacturing new technologies	
Number of graduates in Life Sciences/STEM	• Annual number of graduates in life sciences/STEM fields from higher education institutions and relative growth compared to global competitors.
Global share of clinical trials	• EU's share of active and completed clinical trials.
Total number of employees	• Total number of Full-Time Equivalent (FTE) in pharmaceutical R&D and manufacturing across the EU.

Total annual investment in new manufacturing facilities	• Total amount of money invested annually in the construction, expansion, and modernisation of manufacturing facilities within the EU.
Delivering for society and the economy through investment in health	
Time to market	• Time taken between regulatory approval and availability (EFPIA W.A.I.T indicator).
Adoption of new technologies	• Rates of adoption of new technologies such as CRISPR, AI, and precision medicine within the sector.
Effect of healthcare investment	• Direct employment multiplier: Measures the number of jobs directly created in the healthcare sector per unit of investment. • Indirect employment multiplier: Accounts for jobs created in ancillary sectors due to healthcare investment, such as construction, medical equipment, and services. • Fiscal impact: Evaluates tax revenue generated from increased employment and economic activity due to healthcare investments.
Securing Europe's place as a global biopharma player	
EMA approvals	• Number of authorised medicines compared to other regions. • Use of expedited pathways.
Foreign Direct Investment (FDI)	• Volume and number of foreign direct investment projects in the life sciences sector.
Trade agreements	• Agreements between the EU and third countries to support supply chain resilience.

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#WeWontRest

We've imagined, now let's take action.

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